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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Yinghui Dan

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EXAMINER

ROBINSON, KEITH O NEAL

ART UNIT

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1638

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/064,001	Applicant(s) DAN ET AL.	
	Examiner KEITH O. ROBINSON	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 August 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Applicant's amendment of claims 2-12, filed October 27, 2008, have been received and entered in full.
2. Claims 1-16 are under examination.

Response to Arguments

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-16 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bowen et al (U.S. Patent No. 5,736,369, April 7, 1998), in view of Zhong et al (Planta 187: 483-489, 1992), in view of Weeks et al (Plant Physiol 102: 1077-1084, 1993), in view of Poehlman et al (Molecular biology: Application in plant breeding, Chapter 8. *In* Breeding Field Crops, 4th ed., 1995, pages 132-155), in view of Cheng et al (Plant Physiol 115: 971-980, 1997). The rejection is maintained for the reasons of record as set forth on pages 3-11 of the Office Action mailed June 27, 2008. Applicant's arguments, filed October 27, 2008, have been fully considered but are not found persuasive.

Applicant argues Bowen et al do not teach or suggest all of the claimed features of claim 1, parts b-c (see page 6, lines 1-3 of 'Remarks' filed October 27, 2008).

This is not persuasive. Bowen et al teach culturing explants in a multiple bud inducing media (see, for example, column 7, lines 62-65) and introducing exogenous DNA into a plurality of meristems (see, for example, column 2, lines 45-46).

Applicant argues that present claim 1(c) does not recite introducing DNA into meristems, but instead relates to introducing DNA into a plurality of buds which are not equivalent structures to meristems; thus, the transformation targets of Bowen et al are not the same as that of the present application (see page 6, line 7 to page 7, 1st paragraph of 'Remarks' filed October 27, 2008).

This is not persuasive. MPEP 2141 (III) teaches, “[p]rior art is not limited just to the references being applied, but includes the understanding of one of ordinary skill in the art...[and]...the mere existence of differences between the prior art and an invention does not establish the invention’s nonobviousness. *Dann v. Johnston*, 425 U.S. 219, 230, 189 USPQ 257, 261 (1976). The gap between the prior art and the claimed invention may not be “so great as to render the [claim] nonobvious to one reasonably skilled in the art.”*Id.* In determining obviousness, neither the particular motivation to make the claimed invention nor the problem the inventor is solving controls. The proper analysis is whether the claimed invention would have been obvious to one of ordinary skill in the art after consideration of all the facts”.

Though buds and meristems are not equivalent structures, there is no evidence that the method taught by Bowden et al cannot be used with buds. In fact, Bowen et al

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teach that exogenous DNA can be introduced into meristems and the specification teaches that “[a]ny type of vegetative meristem explant can be used in accordance with this invention” (see page 5, paragraph 0029). In addition, the specification teaches, “[a]xillary meristem refers to...coleoptile node bud, first leaf bud...” (see page 3, paragraph 0016); thus, it would have been obvious to one of ordinary skill in the art to introduce exogenous DNA into a plurality of buds. In addition, claim 7 of Bowen et al would render obvious this method step. The claim language of the instant application is open, thus, the steps need not be practiced in the exact same order.

Applicant argues that the media used by Bowen et al is a meristem culture media wherein the claimed invention is directed to a bud inducing media suitable for inducing production of a plurality of buds from at least one meristem (see page 7, 2nd paragraph of 'Remarks' filed October 27, 2008).

This is not persuasive. Bowen et al teach culturing explants in a multiple bud inducing media (see, for example, column 7, lines 62-65 where it states, “a shoot multiplication medium will utilize a cytokinin, such as Kinetin, BAP, Thidiazuron or Zeatin, at a concentration between 0.5 and 10 mg/l...[and] [a] low level of auxin also may be required in some genotypes”). The specification teaches that a multiple shoot inducing media comprises “a basal plant tissue culture media supplemented with a cytokinin and an auxin” (see page 6, paragraph 003). It would have been obvious to one of ordinary skill in the art that different media can be used depending on the type of plant part used in the claimed method.

Applicant argues that all the limitations of claim 13 are not taught by Bowen et al and no other references are cited in regard to claim 13 (see page 8, 1st paragraph of 'Remarks' filed October 27, 2008).

This is not persuasive. Bowen et al teach a method of producing transgenic cereal plants from a single explant. See, for example, column 2, lines 24-51 where it teaches a method for producing transgenic cereal plants and provides examples of cereal plants wherein wheat is listed as one such example. Thus, it would have been obvious to one of ordinary skill in the art that a wheat mesocotyl explant could have been used in the claimed invention.

Applicant argues that the Zhong et al reference does not describe the use of a mesocotyl explant or wherein the meristems contain a scutellar node, but rather that Zhong et al describes identification and excision of a shoot apex of a recently germinated seed in part by using the presence of the mesocotyl as a positional marker (see page 8, last paragraph to page 10, lines 1-8 of 'Remarks' filed October 27, 2008).

This is not persuasive. Zhong et al teach plurality of meristems containing the scutellar node. See, for example, page 483, 2nd column, last paragraph where it teaches “[t]he position of the shoot tip of the seedling inside the coleoptile could be determined by the localized enlargement of the seedling at the junction of mesocotyl and coleoptile”. The specification teaches, “mesocotyl refers to the internode between and including the scutellar node, and the coleoptile” (see page 5, paragraph 0029). The specification also teaches “[m]eristem tissue is a tissue that produces cells that undergo differentiation to form mature tissues” (page 5, paragraph 0029). It would have been obvious to one of

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ordinary skill in the art that the explants of Zhong et al would comprise meristematic tissue . In addition, Zhong et al teach maize mesocotyl explant (see, for example, page 483, 2nd column, 2nd paragraph). It would be obvious to one of ordinary skill in the art that wheat mesocotyl explant can be used in the method taught by Zhong et al based on the above teachings of Bowen et al that maize and wheat are both monocotyledonous plants. Finally, though Zhong et al do not teach excision of a mesocotyl explant, Zhong et al do teach excision of a shoot tip, leaf primordia and a portion of young leaf and stem below the leaf primordia; thus, excision of a mesocotyl explant would have been obvious to one of ordinary skill in the art.

Applicant argues that Zhong et al do not inherently teach multiple meristems, but rather if multiple meristems are eventually utilized it is only after subsequent shoot multiplication culture of the initial explant tissue (see page 10, 2nd paragraph to page 11, lines 1-3 of 'Remarks' filed October 27, 2008).

This is not persuasive. Zhong et al teach "[o]ur work shows that the corn-shoot meristem can be committed to form either clumps of multiple shoots or somatic embryos in vitro by manipulating the concentrations of BA [cytokinin] and 2,4-D [auxin] in the culture medium" (see page 488, 1st column, last paragraph). Also, see, for example, page 484, Figure 1 where it depicts culturing explants in a multiple bud inducing media. Thus, it would have been obvious to one of ordinary skill in the art that Zhong et al teach multiple meristems.

Applicant argues that the claimed invention yielded surprising, unexpected and unpredictable results in light of the cited references or the art in general (see page 11, 1st paragraph to page 12, line of 'Remarks' filed October 27, 2008).

This is not persuasive. MPEP 716.02 states, "[a]ny differences between the claimed invention and the prior art may be expected to result in some differences in properties. The issue is whether the properties differ to such an extent that the difference is really unexpected". The teaching of unexpected results must be supported by actual data.

In the instant case, it would have been obvious to one of ordinary skill in the art that there would be differences between the claimed invention and the Bowen et al reference because the claimed invention uses wheat lines and the Bowen et al reference uses maize lines.

4. Claims 1-16 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Fry et al (U.S. Patent No. 5,631,152, May 20, 1997), in view of Eudes et al (U.S. Patent No. 6,995,016, which is a continuation-in-part of application 09/641,243, filed August 17, 2000). The rejection is maintained for the reasons of record as set forth on pages 12-15 of the Office Action mailed June 27, 2008. Applicant's arguments, filed October 27, 2008, have been fully considered but are not found persuasive.

Applicant argues that Fry et al do not teach or suggest culturing an explant on a multiple bud inducing media (see page 12, 2nd paragraph to page 13, lines 1-4 of 'Remarks' filed October 27, 2008).

This is not persuasive. Fry et al teach, "[t]he medium used...can be any medium which permits the formation of shoots from regenerable tissue" (see, column 4, lines 44-45). Thus, it would have been obvious to one of ordinary skill in the art to culture explants on a multiple inducing media.

Applicant argues that Eudes et al do not cure the alleged defects of Fry et al because Eudes et al relates only to culturing immature scutella cells from embryos or callus through direct or indirect embryogenesis (see page 13, 1st paragraph of 'Remarks' filed October 27, 2008).

This is not persuasive. Eudes et al does not have to cure the alleged defects because, as discussed above, Fry et al teach culturing explants on multiple inducing media.

Applicant argues that the media being discussed by Eudes et al is a callus induction medium (see page 13, 1st paragraph of 'Remarks' filed October 27, 2008).

This is not persuasive. As stated above, Fry et al teach that any medium which permits the formation of shoots from regenerable tissue can be used in the method as taught by Fry et al.

Applicant argues that Eudes et al teaches away from the present method regardless of the ingredients of any culture medium being described therein and that a skilled worker would have no expectation of success in utilizing the teachings of Eudes

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et al (see page 13, last paragraph to page 14, lines 1-2 of 'Remarks' filed October 27, 2008).

This is not persuasive. As stated above, Fry et al teach that any medium which permits the formation of shoots from regenerable tissue can be used in the method as taught by Fry et al.

Applicant argues Eudes et al mention an organogenic approach and does not suggest wheat; thus, Eudes et al does not recognize that multiple meristems or additional buds may be formed in the presence of cytokinin in wheat (see page 14, 1st paragraph of 'Remarks' filed October 27, 2008).

This is not persuasive. The passage Applicant refers to that mentions an organogenic approach was only a background on organogenesis. In addition, Eudes et al does teach wheat (see, for example, column 23, line 59 to column 24, line 3) as well as Fry et al (see, for example, column 6, lines 10-27). Furthermore, Eudes teaches "[o]ther variants of basal MS medium are also known" and teaches one such medium that contains 2,4-D and BAP (see column 5, lines 12-14). The specification teaches that 2,4-D is an auxin and BAP is a cytokinin (see page 7, paragraph 0034) and that a multiple shoot inducing media comprises a basal plant tissue culture media supplemented with a cytokinin and an auxin (see page 6, paragraph 0033); thus, Eudes et al teach a medium that contains both a cytokinin and an auxin. One of ordinary skill in the art would understand that Eudes et al can be combined with Fry et al to teach the claimed method because Fry et al teaches, "any culture medium...can be used" with the

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invention taught by Fry et al and thus, Fry et al teach how the present result might be achieved.

Applicant argues that there is no reasonable expectation of success in combining the teachings of Fry et al and Eudes et al (see page 14, 2nd paragraph of 'Remarks' filed October 27, 2008).

This is not persuasive. One of ordinary skill in the art would use the teachings of Fry et al as discussed on pages 8-10 of the Office Action mailed February 12, 2007 in combination with the teachings of Eudes et al to yield efficient methods for producing transgenic wheat plants. Fry et al teach the culturing of calli on a modified MS medium (see column 3, lines 45-50); Fry et al teach the introduction of exogenous DNA into embryogenic callus (see column 3, lines 64-65); Fry et al teach removing the transformed embryogenic callus from the first media to a second media suitable for induction of the regenerable tissue into shoots (see column 4, lines 23-39); Fry et al teach culturing the transformed shoots to produce multiple transgenic wheat plants (see column 4, lines 44-55); Fry et al teach the use of auxin (see column 3, lines 45-50) and Fry et al teach harvesting and transferring said shoots to a culture medium that promotes root development (see column 5, lines 21-22). Fry et al do not teach using cytokinins in a bud inducing media; however, Eudes et al teach a medium that contains both a cytokinin and an auxin as discussed above. Thus, one of ordinary skill in the art would have had reasonable expectation of success in combining the teachings of Fry et al and Eudes et al in producing a method for producing multiple transgenic wheat plants from a single explant.

Applicant argues that the claimed method allows a substantial and unexpected increase in the efficiency of the transformation process (see page 14, last paragraph to page 15, lines 1-17 of 'Remarks' filed October 27, 2008). See below.

This is not persuasive. MPEP 716.02 states, "[a]ny differences between the claimed invention and the prior art may be expected to result in some differences in properties. The issue is whether the properties differ to such an extent that the difference is really unexpected". The teaching of unexpected results must be supported by actual data.

Applicant argues that the citation of MPEP 2144.09 at page 13 of the Action is inapposite because it relates specifically to chemical compounds and no compositions are being claimed here (see page 15, last paragraph to page 16, lines 1-2 of 'Remarks' filed October 27, 2008).

This is not persuasive. The citation was used in reference to the Eudes et al reference and its teaching of bud inducing media in that the claimed bud inducing media was suggested by and structurally similar to the prior art media. Eudes et al teach a basal media that contains both a cytokinin and an auxin and the specification teaches that a multiple shoot inducing media comprises a basal plant tissue culture media supplemented with a cytokinin and an auxin.

Applicant argues that Eudes et al is only a general teaching of cytokinins and is discussing an embryogenic approach for creating cultured wheat plant; thus, one skilled in the art would not apply, with any expectation of success conditions for embryogenic

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culture while trying to achieve organogenesis (see page 16, 1st paragraph of 'Remarks' filed October 27, 2008).

This is not persuasive. Regardless of the generality of the teaching of cytokinins by Eudes et al, Eudes et al teaches the importance of cytokinins and its use in media, as discussed on page 14 of the Office Action mailed June 27, 2008.

Applicant argues that the teachings of Fry et al is only of the most speculative, cursory and general of sort and would not give a skilled artisan any expectation of success and the that the Examiner has used hindsight reasoning in making the argument (see page 16, last paragraph of 'Remarks' filed October 27, 2008).

This is not persuasive. It is the combination, not Fry et al alone, that would give a skilled artisan any expectation of success, as stated above. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Double Patenting

5. Claim 1 remains rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 7 of U.S. Patent No.

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5,631,152. The rejection is maintained for the reasons of record as set forth on pages 15-16 of the Office Action mailed June 27, 2008. Applicant's arguments, filed October 27, 2008, have been fully considered but are not persuasive.

Applicant argues that Fry et al does not create a *prima facie* case of obviousness and cannot be the basis for an obviousness-type double patenting rejection (see page 17, 1st paragraph of 'Remarks' filed October 27, 2008).

This is not persuasive. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of said patent read on a method for producing transformed wheat comprising culturing of plant tissue, introducing exogenous DNA, and culturing shoots to produce plants wherein the steps are similar to those of the instant application.

Conclusion

6. No claims are allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KEITH O. ROBINSON whose telephone number is (571)272-2918. The examiner can normally be reached Monday – Friday, 7:30 a.m. - 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Keith O. Robinson
/David H Kruse/
Primary Examiner, Art Unit 1638
30 January 2009